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GUARDANT HEALTH, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GUARDANT HEALTH, INC., a Delaware corporation, Plaintiff, vs. NATERA, INC., a Delaware corporation, Defendant.	Case No. 21-cv-04062-EMC **DECLARATION OF JUSTIN ODEGAARD M.D., PHD, IN SUPPORT OF PLAINTIFF'S MOTION FOR TEMPORARY RESTRAINING ORDER** Date: June 3, 2021 Time: 1:45 p.m. (Pacific Time) Courtroom: Zoom Webinar Complaint Filed: May 27, 2021

I, Justin Odegaard, M.D., Ph.D., declare as follows:

1. I am the Vice President for Clinical Development at Guardant Health, Inc. ("Guardant"). I make this declaration in support of Guardant's Motion for Temporary Restraining Order. As Guardant's Vice President for Clinical Development at Guardant Health, Inc., I have personal knowledge of the facts set forth in this Declaration, and if called to testify as a witness, could and would competently testify to them under oath.

2. Guardant has a mission: To conquer cancer with data. Through painstaking research, Guardant developed its Guardant360 assay which pioneered liquid biopsy. The Guardant360 platform identified and coded strands of dying tumor DNA circulating in a patient's blood to determine the genomic alterations or mutations that drive the cancer.

3. Liquid biopsies are largely used today as a tool for therapy selection for patients

with advanced cancers. However, Guardant continues to work to advance the technology underlying Guardant360 to a point where it can become a tool for early detection of cancers or their recurrence, and a replacement for tissue biopsies that have been historically used to profile cancer tumors.

4. Historically, the field of cancer oncology has been data-starved, i.e., there has not been much data available about the genomic alterations that drive cancer, nor those that develop during cancer evolution. Because it is non-invasive, Guardant360 makes it much easier to capture data about genomic alterations that emerge in response to treatment and over time, and to share that data with others in the scientific and medical community.

5. Using data it has collected from the more than 200,000 patients whose cancers have been sequenced using Guardant360, Guardant is building a massive database of genomic information encompassing a broad variety of cancers, and hopes to increase its dataset to include data from more than 1 million patients over the next five years. This database will help researchers better define various diverse cancers at a molecular level with higher and higher resolution. The more detail this database contains, the more insight it provides into cancer pathogenesis. Guardant believes this resource accelerates new drug development, influences and informs oncologists' decision making, and ultimately improves cancer treatment and management by enabling highly individualized treatments based on comprehensive molecular information. This database also informs research into early detection, which holds tremendous promise for positively impacting survival in most cancers, for which reason the World Economic Forum (Davos) declared liquid biopsy their #1 breakthrough technology for 2017.

6. I joined Guardant as its Medical Director and Laboratory Director in February 2016, and I have served as Guardant's Vice President for Clinical Development since July 2018. Prior to joining Guardant, I was Laboratory Director at OneOme, a company co-founded by the Mayo Clinic and a pioneer in the field of pharmacogenomics, helping improve patient outcomes and reducing healthcare expenses by optimizing personal care medicine. Prior to that I was the Director of Molecular Pathology at Lifecode, Inc., a company focused on pan-cancer genomic analyses for cancer care. In all of my positions, including currently at Guardant, my research has

focused on the development and clinical application of molecular diagnostics.

7. I am a board-certified molecular and surgical pathologist, and I hold a Ph.D. in Immunology and an M.D. from Stanford University School of Medicine, where I also served as an adjunct clinical professor of pathology.

8. As Guardant's Vice President for Clinical Development, I oversee advanced cancer clinical strategy; clinical trial operations, including design, execution, and submission of strategic clinical studies; and clinical laboratory testing including clinical aspects of assay development and validation, regulatory submission and medical policy.

9. My most recent Curriculum Vitae is attached hereto as **Exhibit 1.**

10. Guardant is a pioneer in non-invasive cancer diagnostics and was the first company to commercialize a comprehensive genomic liquid biopsy blood test that is used to profile and track tumor genomics and identify treatment options. The Guardant oncology platform leverages its capabilities, including its proprietary blood tests, exclusive fragment coding, vast data sets, and advanced analytics, to drive commercial adoption, improve patient clinical outcomes, and lower healthcare costs across all stages of the cancer care continuum. Guardant Health has commercially launched the liquid biopsy-based Guardant360®, Guardant360® CDx, and GuardantOMNI® tests for advanced stage cancer patients, and recently launched its Guardant Reveal™ test for early-stage colorectal (CRC) patients.

11. CRC is the third most commonly diagnosed cancer and the second leading cause of cancer death in the United States. While a majority of patients are diagnosed with early-stage disease, nearly a third of patients whose CRC spreads into adjacent tissues and lymph nodes will die from their disease within five years.

12. Surgery alone is often curative for early-stage CRC, and in later-stage cases, adjuvant chemotherapy after surgery can reduce the risk of recurrence. However it is unclear which patients need adjuvant chemotherapy, and many who receive it do so unnecessarily. Until recently, clinicians have had very limited means of identifying patients that require adjuvant chemotherapy. Thus, the development of effective clinical tests to identify CRC patients with Minimal Residual Disease (MRD)—i.e., a small number of CRC cells remaining in the body that

can later multiply and cause recurrence of the disease—after surgery has long been recognized as a need, to help doctors both identify patients who may benefit from additional therapy and avoid administering unnecessary and toxic treatment to patients who will not benefit from it.

13. Human blood contains fragments of DNA, called cell-free DNA (cfDNA) that are shed into the bloodstream by dying cells in tissues. Such fragments of dying cancer cells are known as circulating tumor DNA (ctDNA). This phenomenon led to the development of so-called "liquid biopsies" a game-changing technology capable of detecting the presence of cancer in patients by detecting ctDNA in their blood without need of tumor tissue itself. This eventually led to liquid biopsies specifically designed to assess MRD following treatment of CRC. Liquid biopsies using simple blood draws offer major advantages for identifying MRD, because they are quick, convenient, and minimally invasive, and can be easily repeated to monitor for the presence of ctDNA over time.

14. Detecting and characterizing the very low concentrations of ctDNA present in the blood of CRC patients with MRD, and using that information to stratify patients as high- or low-risk for recurrence, requires an assay that is both highly sensitive and specific. Recognizing this need, Guardant expended substantial resources and time to develop Reveal, a clinical blood-based assay to evaluate ctDNA in blood using advanced DNA sequencing methods.

15. Reveal is the first commercially available plasma-only ctDNA assay, capable of detecting MRD in post-operative CRC patients without the need for prior sampling and sequencing of tumor tissue or the time needed to create a new, customized test for each new patient. Reveal simultaneously interrogates genomic and epigenomic alterations. It accurately identifies genomic alterations down to allele frequencies of 0.01%, and effectively filters out biological noise sources such as mutations caused by clonal hematopoiesis that can lead to false positive results when testing for MRD. The incorporation of biologically relevant epigenomic signatures is a key feature of Reveal that increases its test sensitivity in post-curative intent and surveillance indications.

16. Peer-reviewed data from a study conducted by Dr. Aparna R. Parikh and her colleagues at Massachusetts General Hospital Cancer Center shows that longitudinal Reveal

testing offers 91% sensitivity for recurrence (i.e., Reveal identified 91% of patients who went on to recur based on ctDNA detection) and 100% positive predictive value[1] for recurrence (i.e., all patients Reveal identified as having a "positive" ctDNA test result later recurred). This data has been presented at the 2019 American Society of Clinical Oncology (ASCO) meeting and the 2019 and 2020 European Society for Medical Oncology (ESMO) conference and was recently published in the April 29, 2021 on-line issue of the journal *Clinical Cancer Research*.

17. This performance makes Reveal a useful tool in the management of early stage CRC patients, however Reveal offers meaningful advantages over existing assays for detecting MRD in CRC patients as well. Currently, the only other commercialized assay for detecting MRD in CRC patients of which I am aware is Natera, Inc.'s Signatera™. Signatera is a tumor-dependent assay (Natera uses the term "tumor-informed") that sequences tumor tissue to identify a panel of tumor mutations specific to that patient, which then can be monitored throughout the patient's disease course.

18. Tumor-dependent assays like Signatera have drawbacks. Specifically, a meaningful number of CRC patients—particularly those treated with chemotherapy prior to surgery—may not have sufficient samples of tumor tissue to allow initial genomic profiling of the tumor. For these patients, a plasma-only ctDNA assay like Reveal provides the only option for MRD detection using ctDNA. Even if sufficient tissue is available, the need to profile the tissue and develop an individualized array of assays can create significant delays in initial MRD testing turnaround time. Reveal obviates the dependency on tissue and reduces the time to attain results needed to decide whether high-risk patients require adjuvant chemotherapy from approximately three weeks to just 7 days. For patients with a potentially lethal disease like CRC, this timely therapy decision-making is critical for both outcomes and for peace of mind.

19. But the importance of plasma-only, tissue-independent analyses goes beyond the acceleration of time to result performance. For some groups of patients it is a fundamental matter

[1] Positive predictive value (PPV) refers to the assay's ability to correctly predict which patients will subsequently develop a recurrence of CRC (i.e., "positive" test result means CRC will recur).

of access. As some patients may not have adequate tumor tissue available for sequencing. This can occur in early stage cancers when patients have received neoadjuvant chemotherapy, which can kill the tumor in tissue samples, and when tissue samples are either unavailable due to logistical reasons (e.g. patient referred from another facility) or inadequate in either quantity or quality for follow-on MRD testing. Without Reveal, these patients would be deprived of early recurrence detection and would be consigned to the traditional clinical risk stratification, which may result in over- or under-treatment.

20. To be meaningful, any comparison between diagnostic tests, including ctDNA assays for detecting MRD in CRC patients must be supported by properly designed, head-to-head studies that directly compare the two assays using the same test procedures and protocols in the same patient population. Cross-test comparisons, especially where the purpose and methodology of the underlying studies differ significantly, and/or where the studies are conducted in different patient populations, are fraught with, and often result in, misleading apples-to-oranges comparisons that cannot legitimately be used to claim that one test is superior to the other.

21. As of this declaration, I am unaware of any such independent, head-to-head studies, that could be used to compare the performance of commercially available products—Reveal to Signatera—using the same test protocol and procedures in the same patient population.

22. Nonetheless, I am aware of the litany of Natera promotional materials that discusses such comparisons and touts the superiority of Signatera compared with Reveal and the alleged superiority of "tumor informed" assays over "tumor naïve" assays in general in detecting MRD. Some of these advertisements include their "Evidence Review;" their "White Paper;" and their "Investor Presentation," which purports to compare "Signatera vs. Reveal performance." Similar to its "Evidence Review" and "White Paper," Natera's May 2021 "performance comparison" claims to demonstrate quantitatively that Signatera is superior to Reveal across a wide-ranging set of metrics, including "pre-surgical sensitivity," "failure rate," "diagnostic lead time," "post-surgical" and "serial longitudinal" negative predictive value (NPV), and "Hazard Ratio," among other categories, some of which are not "performance" metrics at all.

23. Critically Natera's "performance comparisons" are not based on a head-to-head study directly comparing Signatera and Reveal. No such study has been submitted, reviewed nor published to my knowledge. Instead Natera cites select data from a study conducted by Reinert *et al.* ("the Reinert Study") concerning Signatera, and inappropriately extrapolates other data from a study of an entirely different design and patient population conducted by Parikh *et al.* ("the Parikh Study") concerning Reveal. Published versions of both studies are attached as Exhibits I and J to the Declaration of Thereasa Rich, M.S.

24. Natera's advertising misleads oncologists and other physicians, cancer researchers, health care institutions, biopharmaceutical companies, and genetic laboratories to believe that Reveal is not validated, unproven, insensitive, and indeed "detrimental to patients," and that Signatera provides superior "performance."

25. In addition to clinical applications, I have (and currently do) work closely with our Biopharma business development team. That group works with companies developing cancer therapeutics, including small molecule drugs, immunological response biologics, and other advanced biochemical agents of treatment or remedy. Reveal, like the other Guardant assays, serve an important role in the development and validation of new therapeutics.

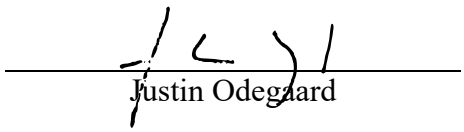
26. Biopharma companies run clinical trials to determine the safety and efficacy of proposed therapeutics. Populating those trials with patients who meet the test criteria is often a long and arduous process. For example, if a study wished to test a therapy on a CRC patient who could benefit from adjuvant therapy, it would aim to populate the study with patients who would otherwise experience post-surgical recurrence.

27. Reveal is intended to identify CRC patients who would have future disease recurrence and thereby allowing those patients access to late-stage drugs or biologics that could be effective in preventing that recurrence. In other words, Reveal becomes the gateway to a clinical trial for the patients most likely to validate the efficacy of the test.

28. I am aware that at least one biopharma company has been shown the Natera-authored comparison chart that contains many of the false and misleading assertions about Reveal. Guardant was specifically called to stand and defend the assertions put forth by Natera.

29. Oncologists do not have the means, resources or opportunities to independently test and validate new technology. As a result, they must rely on the accuracy of information placed before them by medical liaisons, sales representatives, promotional publications, and information presented at public meetings such as ASCO, among others. Recognizing the importance of objective measures to the community of oncology clinicians, Natera has used misrepresented simulacra of such measures to mislead them into believing that the risks of adopting Reveal outweigh the potential benefits, and in doing so, have deprived patients of the benefits of the platform.

Pursuant to 28 U.S.C. § 1746, I, Justin Odegaard, certify under penalty of perjury that the foregoing is true and correct. Executed on this 2nd day of June, 2021.



Justin Odegaard

EXHIBIT 1

JUSTIN ODEGAARD, MD, PHD

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SUMMARY

Physician-scientist with executive experience in molecular diagnostics, including laboratory director and vice president roles leading clinical development, validation, operation, and clinical interpretation of molecular oncology diagnostics (IVD and CDx). Built companion diagnostics and clinical trial operations groups from ground up through two FDA Breakthrough Device Designations, multiple successful Investigational Device Exemptions, approval of the first liquid biopsy panel, approval of multiple PMA and sPMA CDx devices in US, Japan, and EU, including co-developed and follow-on CDx. VP-level experience in clinical strategy, including clinical product development, diagnostic study design and execution, and data development. VP-level experience contributing to reimbursement strategy, including clinical lead for successful Medicare and private payer coverage efforts.

EMPLOYMENT EXPERIENCE

Guardant Health (Redwood City, CA)
Vice President Clinical Development, August 2018 – Present
Senior Medical Director, Laboratory Co-Director, February 2016 – August 2018

Stanford University, Department of Pathology (Stanford, CA)
Instructor of Pathology (Attending Physician, Molecular Genetic Pathology), July 2013 – Jan. 2017
Adjunct Assistant Clinical Professor, Jan 2017 – May 2020

OneOme (Minneapolis, MN)
Laboratory Director, February 2016 – February 2018

LifeCode/Silicon Valley Biosystems (Foster City, CA)
Laboratory Director designee, Director of Molecular Pathology, June 2014 – January 2016

University of California San Francisco, Cardiovascular Research Institute (San Francisco, CA)
Assistant Professional Researcher, July 2013 – May 2016

Driver Group, LLC (San Francisco, CA)
Diagnostics development consultant, June 2015 – November 2015

CLINICAL TRAINING

Stanford University Hospital, Department of Pathology (Stanford, CA)
Molecular and genetic pathology fellow, July 2012 - June 2013
Surgical pathology fellow and chief resident, July 2011 - June 2012
Anatomic pathology resident, July 2009 - June 2011

PROFESSIONAL CERTIFICATIONS

New York State, Clinical Laboratory Evaluation Program Laboratory Director Certificate of Qualification in Molecular and Cellular Tumor Markers and Genetic Testing

American Board of Pathology diplomate in molecular and genetic pathology and anatomic pathology

California State Medical Board medical license #A113725

EDUCATION

Stanford University Medical School (Stanford, CA): M.D., June 2009, Ph.D. (Immunology), June 2009

Duke University (Durham, NC): B.S., June 2002

PATENTS

Primary Inventor, GH0034US-PRV2/42534-784.102, "Methods for the non-invasive detection and monitoring of therapeutic nucleic acid constructs."

Inventor, GH0041WO/42534-794.601, "Methods and systems for adjusting tumor mutational burden by tumor fraction and coverage."

PUBLICATIONS (IN REVERSE CHRONOLOGICAL ORDER)

ORIGINAL RESEARCH

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3. Evaristus C. Mbanefo; Loc Le; Luke F. Pennington; Yi-Ju Hsieh; Justin I. Odegaard; Kristina Lapira; Theodore S. Jardetzky; Franco H. Falcone; Michael Hsieh. "IPSE, a Urogenital Parasite-Derived Immunomodulatory Molecule, Suppresses Bladder Pathogenesis and Anti-Microbial Peptide Gene Expression in Bacterial Urinary Tract Infection." ***Parasites & Vectors.*** In press.
4. Evaristus C. Mbanefo, PhD; Chinwike Terry Agbo, MD; Yuanlong Zhao, MD; Olivia K. Lamanna, BS; Kimberly H. Thai, MD; Shannon Karinshak; Mohammad Khan; Chi-Ling Fu; Justin Odegaard; Irina Saltikova; Michael Smout; Luke Pennington; Mark Nicolls; Theodore Jardetzky; Alex Loukas; Paul Brindley; Franco Falcone; Michael Hsieh. "IPSE, an Abundant Egg-Secreted Protein of the Carcinogenic Helminth Schistosoma haematobium, Promotes Proliferation of Bladder Cancer Cells and Angiogenesis." ***Infectious Agents and Cancer.*** In press.
5. Yoshiaki Nakamura, Hiroya Taniguchi, Masafumi Ikeda, Hideaki Bando, Ken Kato, Chigusa Morizane, Taito Esaki, Yoshito Komatsu , Yasuyuki Kawamoto , Naoki Takahashi, Makoto Ueno, Yoshinori Kagawa, Tomohiro Nishina, Takeshi Kato, Yoshiyuki Yamamoto, Junji Furuse, Tadamichi Denda, Hisato Kawakami, Eiji Oki, Takako Nakajima, Naohiro Nishida, Kensei Yamaguchi, Hisateru Yasui, Masahiro Goto, Nobuhisa Matsuhashi, Koushiro Ohtsubo, Kentaro Yamazaki, Akihito Tsuji, Wataru Okamoto, Katsuya Tsuchihara, Takeharu Yamanaka, Izumi Miki, Yasutoshi Sakamoto, Hiroko Ichiki, Masayuki Hata, Riu Yamashita, Atsushi Ohtsu, Justin I. Odegaard, Takayuki Yoshino. "Clinical Utility of Circulating Tumor DNA Sequencing in Advanced Gastrointestinal Cancer: SCRUM-Japan GI-SCREEN and GOZILA Studies." ***Nature Medicine.*** 2020 Dec; 26(12):1859-1864. Epub Oct 5 2020.
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9. Willis J, Lefterova MI, Artyomenko A, Kasi PM, Nakamura Y, Mody K, Catenacci DVT, Fakih M, Barbacioru C, Zhao J, Sikora M, Fairclough SR, Lee H, Kim KM, Kim ST, Kim J, Gavino D, Benavides M, Peled N, Nguyen T, Cusnir M, Eskander RN, Azzi G, Yoshino T, Banks KC, Raymond VM, Lanman RB, Chudova DI, Talasaz A, Kopetz S, Lee J, Odegaard JI. "Validation of Microsatellite Instability Detection Using a Comprehensive Plasma-Based Genotyping Panel." ***Clinical Cancer Research.*** 2019 Aug 4. doi: 10.1158/1078-0432.CCR-19-1324.
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14. Evaristus Mbanefo, Loc Le, Rebecca Zee, Nirad Banskota, Kenji Ishida, Luke Pennington, Justin Odegaard, Theodore Jardetzky, Abdulaziz Alouffi, Franco Falcone, and Michael Hsieh. "IPSE, a urogenital parasite-derived immunomodulatory protein, ameliorates ifosfamide-induced hemorrhagic cystitis through downregulation of pro-inflammatory pathways" ***Nature Scientific Reports,*** 2019, Feb 7;9(1):1586.
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